DEC 23 2009

K690832

X. PREMARKET NOTIFICATION SUMMARY

Submitted by:

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Contact Person:

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Date Prepared:

8 December 2009

Trade Name:

Rapid-i™

Common Name:

Cryopreservation container and microtool

Classification Name:

Assisted Reproduction Labware
(21 C.F.R. § 884.6160)

Product Code:

MQK

Predicate Device:

CryoTip™ (K041562)

Description of the Device:
Rapid-i™ is a modification of the CryoTip™ microtool from Irvine Scientific Sales Co., Inc. (K041562), has similar intended use as the predicate device, and similar technological characteristics related to safety and effectiveness. This submission contains information demonstrating substantial equivalence between these two devices.

Rapid-i™ is a device intended for the vitrification of 4-8 cell stage embryos through vitrification. Rapid-i™ consists of the following two items:

- A Polymethyl Methacrylate (PMMA) stick, 80 mm long and 2 mm in diameter
- A Polyvinyl Chloride (PVC) straw, 165 mm long and 3 mm in diameter, equipped with a stainless steel weight
- The two parts are packed in a TYVEK® bag and sterilised by ionizing radiation

The likelihood of contamination from the liquid nitrogen is very small since the distance is from the surface of the liquid nitrogen to the opening of the straw is at least 50 mm and most of that distance is occupied by air at 20°C. Liquid nitrogen will make the transition to gas at -196°C. It is even more unlikely that any viral contaminants which could be present in the liquid nitrogen would contaminate the embryo of the same reason.

The samples can not thaw when the straw is sealed after placement in liquid nitrogen if the instructions in the Package Insert are followed.

The minimum distance from the surface of the liquid nitrogen and the top of the straw is 45 mm. It is evident from the geometry that the embryo can not come in contact with the straw during insertion or removal. The surface tension keeps the embryo safely in place.

Intended Use
Rapid-i™ is a cryopreservation device that is intended to be used to contain, vitrify and maintain 4-8 cell stage embryos.

Technological Characteristics:
The device Rapid-i™ is a modification of CryoTip™ (K041562). Rapid-i™ has similar intended use as the predicate device (K041562), and similar technological characteristics related to safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

DEC 23 2009

Mr. Kjell Kjörk
Pharmacist, Senior Regulatory Affairs Manager
Vitrolife Sweden AB
Box 9080, SE-400 92, Göteborg
SWEDEN

Re: K090832
Trade/Device Name: Rapid-i™
Regulation Number: 21 CFR 884.6160
Regulation Name: Assisted reproduction labware
Regulatory Class: II
Product Code: MQK
Dated: December 9, 2009
Received: December 11, 2009

Dear Mr. Kjörk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

XI. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K090832

Device Name: Rapid-i™

Indications for Use: Rapid-i™ is a cryopreservation device indicated to be used to contain, vitrify and maintain 4-8 cell stage embryos

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____X____ OR Over-the Counter Use_____
(Per 21 C.F.R. § 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K090832